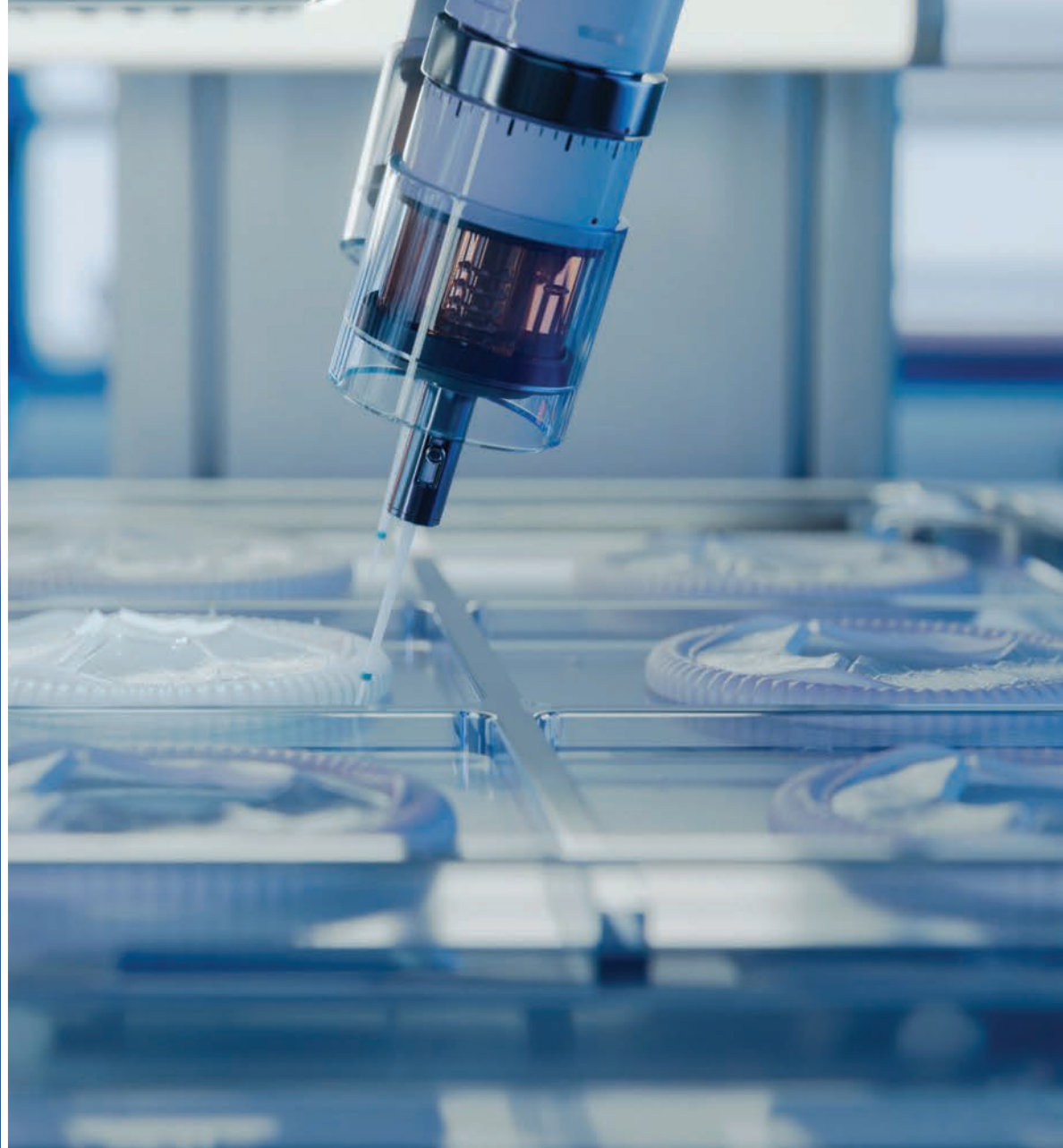




ULTRA-CLEAN ELECTROSTATIC CONTROL

In-Tool and Cleanroom
for Life Sciences
Manufacturing



SIMCO IONTM
An ITW Company



MONITORING

Particulate Contamination in Medical Devices

Static elimination is a critical aspect of medical device manufacturing as it ensures the safety, reliability, and quality of the device. Implementing static elimination measures can help manufacturers reduce the cost of repairs and replacements due to ESA effect, as well as costs associated with cleaning and maintaining equipment.



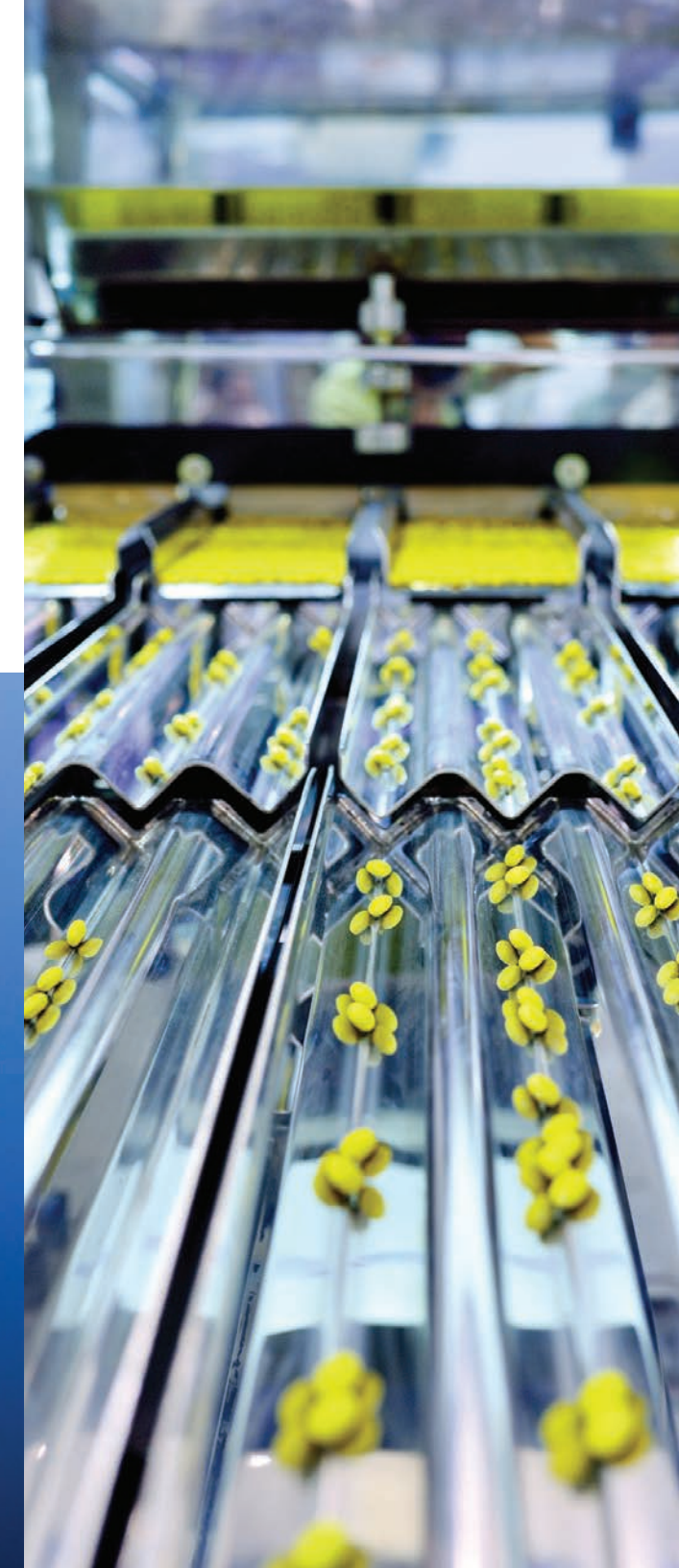
Simco-Ion, Technology Group, a Worldwide Leader in Advanced Ionization and Monitoring Solutions for Ultra-clean and ESD Control applications, is renowned for...

QUALITY. PERFORMANCE. RELIABILITY.

Simco-Ion, Technology Group provides **ULTRA-CLEAN** ionization solutions designed for in-tool and cleanroom applications. Our comprehensive offerings include ionizing bars, room systems, overhead blowers, and in-line technologies, tailored to meet the stringent demands of modern cleanroom environments.

Our ULTRA-CLEAN ionization products effectively address customers' Electrostatic Attraction (ESA) and airborne particle control needs. With clean ionization technology that surpasses the industry's highest standards for contamination control, maintenance, and safety, we ensure optimal performance and reliability.

To guarantee compliance and superior results, our expertly trained technicians ensure that every cleanroom environment not only meets but exceeds FDA regulations.



ESSENTIAL REQUIREMENTS FOR TODAY'S MANUFACTURING INDUSTRIES

Ultra-Clean Environment

In ultra-clean environments where airborne particle control is critical, minimizing Electrostatic Attraction (ESA) is essential. Without proper control, particulates can lead to latent failures, contamination, reduced product quality, and significant yield loss.

Voltage Control

Achieving tighter voltage control is vital to eliminating or reducing Electrostatic Discharge (ESD) in medical electronics manufacturing. ESD can cause active device damage and latent defects. Maintaining precise offset voltage, combined with faster decay times, ensures optimal protection for devices and products during processing in ultra-clean environments.

Advanced Monitoring

Aligned with Industry 4.0 standards, the Novx Electrostatic Control Management System offers real-time monitoring with active feedback and control. This innovative system enhances traceability, ensures compliance, optimizes process management, and provides advanced notifications, empowering manufacturers to maintain peak performance.



Requirements

FDA cleanroom regulations mandate rigorous environmental controls, beginning with the planning and construction stages to ensure compliance with clean air standards. Cleanrooms must include a dedicated monitoring system housed in a separate, adequately sized room equipped to control humidity, dust, air pressure, temperature, and microorganisms. Regulations also require advanced air filtration systems and comprehensive written procedures to prevent contamination, as well as to clean and sanitize all surfaces and equipment.

ULTRA-CLEAN IONIZATION PROTECTION

There are three main factors to consider for any classification of cleanrooms: **airflow**, **human access**, and **surfaces**, and how in-room ionization systems can minimize particulate contamination and electrostatic charge on all production surfaces, on plastic components, and where manufacturing production friction occurs.

1. AIRFLOW

The HVAC system in a cleanroom regulates temperature, humidity, and air quality. It utilizes high-efficiency particulate air (HEPA) filters to remove particles from the air and maintains positive pressure within the cleanroom by ensuring the air pressure inside is higher than the pressure outside. This positive pressure prevents contaminated air from entering the cleanroom. The system also filters and recirculates the air, pushing out any contaminated air through designated vents.

2. HUMAN ACCESS

Humans are the primary source of contaminants in cleanrooms, making proper training essential for maintaining cleanliness standards. All personnel must be thoroughly trained in cleanroom protocols, including proper entry and exit procedures, the use of protective clothing, and correct equipment handling. This ensures compliance with the cleanroom's ISO class requirements and helps minimize contamination risks.

3. SURFACES

All cleanroom surfaces should be smooth, impervious to microorganisms, and compatible with approved cleaning agents and disinfectants. Additionally, the cleanroom should be equipped with a state-of-the-art room ionization system to further reduce contamination risks.

MEDICAL DEVICE MANUFACTURING

CLEANROOM IONIZATION SYSTEM

Model 5515 Room Ionization System protects the cleanroom, gowning room, and entire manufacturing area. The state-of-the-art system comprises ceiling emitters, a controller, and robust software for monitoring capabilities. Digital technology allows each ceiling emitter's parameters—including ion output, ion pulse timing, and address—to be individually set at its location. Precision fine-tuning of each ceiling emitter enables the ionization system to achieve maximum performance in any airflow condition and for each application.

Typical medical applications where ionization and monitoring solutions are essential in improving productivity:

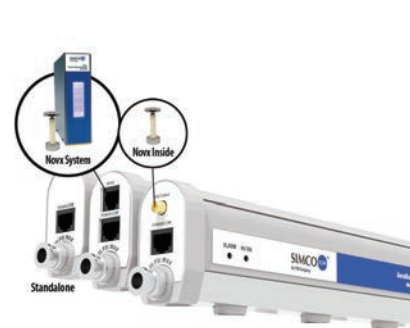
Medical Manufacturing

- In Vitro Diagnostics
- Cardiology
- Implantable Medical Devices
- Orthopedics
- Diagnostic Imaging
- Ophthalmics, and more...



CONTAMINANT REMOVAL SOLUTIONS

Installing ionization room systems is the best way to ensure your cleanroom meets industry standards. Schedule an on-site visit by a trusted Simco-Ion, Technology Group account representative or applications engineer who has experience with all classes of cleanrooms in various industries. Your cleanroom is a significant investment. Rely on us to help you protect that investment, your consumers, and the integrity of your product with customer-backed innovation ionization superior results.



Ionizing Bar



Room Ionization System



Overhead Blower



Benchtop Ionizing Blower

ELECTROSTATIC SENSING AND PROCESS MONITORING



Simco-Ion, Technology Group's Novx Electrostatic Sensing and Process Monitors are designed to detect and analyze electrostatic events in advanced process environments across industries such as semiconductors, life sciences, flat-panel displays, and electronic assembly. Electrostatic discharge (ESD) events can lead to human discomfort and catastrophic or latent damage to sensitive electronic devices. As manufacturing processes become more advanced, the demand for real-time monitoring, data collection, and status reporting is shifting from a preference to a critical requirement. These capabilities are essential for improving manufacturing yields and providing historical data for verification.



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